CLAIMS

WHAT IS CLAIMED IS:

1. A method for detecting in the gastrointestinal tract of a subject the presence of a bacteria which when present in the gastrointestinal tract of the subject is associated with the catalytic degradation of urea to ammonia and carbon dioxide, the method comprising:

(a) delivering a source of urea to the gastrointestinal tract of the subject,

(b) obtaining a fluid sample from the subject after the delivery of the urea source,

(c) combining the fluid sample with an aqueous solution,

(d) contacting the aqueous solution with a sensor after the aqueous solution has been combined with the fluid sample, the sensor comprising a porous hydrophobic polymer having a dye embedded within the pores but not on the exposed surface thereof, the dye being capable of being deprotonated and undergoing a color change in the presence of ammonia, the pores being permeable to ammonia gas derived from the aqueous solution but impermeable to the aqueous solution whereby ammonia gas derived from the aqueous solution can permeate the pores and deprotonate the dye to effect a color change, and

(e) detecting a color change in the sensor after the sensor is contacted with the fluid sample.

2. The method of claim 1 wherein the bacteria causes a gastrointestinal associated disorder in the subject, the gastrointestinal associated disorder being selected from the group consisting of gastritis, peptic ulceration, gastric cancer, non-ulcer dyspesia, duodenal ulcers, gastric ulcers, duodenitis, gastric non-Hodgkin's lumphomas, intestinal metaplasia, adenocarcinoma, and esophagitis.

3. The method of claim 1 wherein the bacteria is a *Helicobacter*.

4. The method of claim 1 wherein the bacteria is *Helicobacter pylori*.

5. The method of claim 1 wherein the fluid sample is selected from the group consisting of a breath sample, a saliva sample, a perspiration vapor sample and a gastric reflux sample.

6. The method of claim 1 wherein the fluid sample is a breath sample.

7. The method of claim 6 wherein the breath sample is an exhaled sample or multiple breath samples.

8. The method of claim 1 wherein the aqueous solution further comprises sodium hydroxide.

9. The method of claim 1 wherein a droplet of water placed on the surface of the hydrophobic polymer has a contact angle of not less than about 100 degrees.

10. The method of claim 1 wherein the polymer has an average pore size of less than about 9 microns.

11. The method of claim 10 wherein the polymer has an average pore size of about 1.0 microns to about 2.5 microns.

12. The method of claim 1 wherein the polymer is selected from the group consisting of polytetrafluoroethylene, polyvinylidene difluoride, acrylic-based polymers, ethylene propylene polymers, polycarbonate, polyproylene, polyvanilidine chloride, dimethyl polysiloxane.

13. The method of claim 1 wherein the polymer comprises polyvinylidene difluoride.

14. The method of claim 1 wherein the dye is selected from the group consisting of bromophenol blue, bromothymol, phenol red, methyl orange, methyl yellow, 2,4-dinitrophenol, 2,6-dinitrophenol, and cresol red.

15. The method of claim 1 wherein the dye is bromophenol blue.

16. The method of claim 1 wherein the sensor changes color within about 5 to about 60 seconds after the porous polymer is permeated with the ammonia gas.

17. The method of claim 1 wherein the subject is administered a mouth wash comprising an antibacterial agent prior to collection of the breath sample to reduce the number of bacteria present in the subject's mouth.

18. The method of claim 1 wherein the concentration of ammonia gas is determined by measuring the color change of the dye with an optical reader.

19. The method of claim 1 wherein the sensor is in the form of a membrane.

20. The method of claim 1 wherein the sensor is in the form of particulate matter.

21. A method to detect the presence of a bacteria in the gastrointestinal tract of a subject, which when present in the gastrointestinal tract of the subject is associated with the catalytic degradation of urea to ammonia and carbon dioxide, the method comprising:

(a) delivering a source of urea to the gastrointestinal tract of the subject,

(b) obtaining a liquid sample from the subject after the delivery of the urea source,

(c) contacting the liquid sample or a derivative thereof with a sensor, the sensor comprising a hydrophobic polymeric material and a dye associated with the polymeric material, the dye having the capacity to become deprotonated and undergo a color change in the presence of ammonia,

(d) controlling the contact conditions such that the sensor responds to the presence of ammonia in the fluid sample but not to the pH of the fluid sample by undergoing an optically discernible color change, and

(e) optically detecting a color change in the sensor after the sensor is contacted with the fluid sample.

22. The method of claim 21 wherein the liquid sample is selected from the group consisting of a saliva sample and a tear sample.

23. A method to detect the presence of a bacteria in the gastrointestinal tract of a subject, which when present in the gastrointestinal tract of the subject is associated with the catalytic degradation of urea to ammonia and carbon dioxide, the method comprising:

(a) delivering a source of urea to the gastrointestinal tract of the subject,

(b) inducing the subject to exhale a breath sample into a container, the container comprising an inlet, a vent, and a sensor, and being adapted to restrict the flow of gas out of the inlet, the sensor comprising a hydrophobic polymeric material and a dye associated with the polymeric material, the dye having the capacity to become deprotonated and undergo a color change in the presence of ammonia,

(d) controlling the contact conditions such that the sensor responds to the presence of ammonia in the breath sample but not to the pH of the breath or any liquid in the container by undergoing an optically discernible color change, and

(e) optically detecting a color change in the sensor after the subject exhales into the container.

24. The method of claim 23 wherein a droplet of water placed on the surface of the hydrophobic polymer has a contact angle of not less than about 100 degrees.

25. The method of claim 23 wherein the polymer has an average pore size of less than about 9 microns.

26. The method of claim 23 wherein the polymer has an average pore size of about 1.0 microns to about 2.5 microns.

27. The method of claim 23 wherein the polymer is selected from the group consisting of polytetrafluoroethylene, polyvinylidene difluoride, acrylic-based polymers, ethylene propylene polymers, polycarbonate, polyproylene, polyvanilidine chloride, dimethyl polysiloxane.

28. The method of claim 23 wherein the polymer comprises polyvinylidene difluoride.

29. The method of claim 23 wherein the dye is selected from the group consisting of bromophenol blue, bromothymol, phenol red, methyl orange, methyl yellow, 2,4-dinitrophenol, 2,6-dinitrophenol, and cresol red.

30. The method of claim 23 wherein the dye is bromophenol blue.

31. A breath sampler for use in detecting the presence of H. pylori in the gastrointestinal tract, the breath sampler comprising a breath handler and a detection unit including a sensor capable of reacting to the presence of an indicator in the breath sample of H. pylori in the gastrointestinal tract, the breath handler being adapted to route air through the breath sampler upon inhalation by the subject to the subject while substantially blocking flow of air through the detection unit to the subject, and being adapted upon exhalation of the subject to route exhaled air through the breath handler to the detection unit for detection of H. pylori in the gastrointestinal tract.

32. A breath sampler as set forth in claim 31 wherein air flow through the detection unit is substantially blocked except upon exhalation by the subject through the breath sampler.

33. A breath sampler as set forth in claim 32 wherein the detection unit is substantially isolated from ambient except upon exhalation by the subject through the breath sampler.

34. A breath sampler as set forth in claim 32 wherein the breath handler includes an air intake, a breath sample opening and a breath sample outlet, the detection unit being arranged to receive air from the breath handler by way of the breath sample outlet, the breath handler receiving ambient air through the air intake upon inhalation by a subject and directing air to the breath sample opening for inhalation by the subject, and blocking a path from the breath sample outlet to the breath sample opening, the breath handler directing exhaled air from the subject to the breath sample outlet and thence to the detection unit, and blocking a path from the breath sample opening to the air intake.

35. A breath sampler as set forth in claim 34 wherein the breath handler comprises a tube having the air intake at one end thereof and the breath sample opening at an opposite end thereof, and a collection branch in fluid communication with the tube and the detection unit and including the breath sample outlet.

36. A breath sampler as set forth in claim 35 wherein the breath handler further comprises a first valve located generally at the air intake end of the tube for permitting inhaled air to flow into the tube but blocking the breath sample from flowing out of the tube through the air intake, and a second valve located in the collection branch for permitting the breath sample to flow from the tube through the collection branch and into the detection unit and blocking flow of air from the detection unit through the collection branch into the tube.

37. A breath sampler as set forth in claim 36 wherein the detection unit includes a vent for exhausting excess exhaled air from the detection unit, and wherein the detection unit further comprises a third valve disposed for permitting exhaust of exhaled air under pressure through the vent from the detection unit and inhibiting the intake of ambient air through the vent from outside the detection unit.

38. A breath sampler as set forth in claim 37 wherein the first, second and third valves are one way valves biased to a closed position in the absence of an air pressure differential across the valves.

39. A breath sampler as set forth in claim 31 further comprising liquid in the detection unit, the breath handler being adapted to discharge the breath sample into the liquid.

40. A breath sampler as set forth in claim 31 wherein the detection unit includes a vent for exhausting excess gas from the detection unit, and the breath handler comprises a tube having an intake end including an air intake and a mouthpiece portion including a breath sample opening, the intake end being positioned to locate the air intake out of registration with the vent to inhibit inhalation of exhausted air from the detection unit.

41. A breath sampler as set forth in claim 40 wherein the breath handler is pivotally mounted in the detection unit.

42. A breath sampler as set forth in claim 31 wherein the breath handler comprises a tube having an intake end including an air intake and a mouthpiece portion including a breath sample opening, the mouthpiece portion being tapered toward the breath sample opening to facilitate reception into the back of the mouth near the throat.

43. A breath sampler as set forth in claim 31 wherein the detection unit comprises a collection receptacle and the sensor is mounted in the collection receptacle, the sensor being adapted to change color upon the detection of said indicator in the breath sample, and the collection receptacle being at least partially transparent to permit a line of sight to the sensor.

44. A breath sampler as set forth in claim 31 wherein the breath sample outlet is arranged relative to the detection unit for directing the breath sample against the sensor.

45. A breath sampler as set forth in claim 31 in combination with a reader arranged for reading the sensor of the detection unit and displaying a readout corresponding to the sensor indication, the reader having a

self contained power source and being adapted for connection together with the breath handler and detection unit when used by the subject to obtain a breath sample.

46. The combination as set forth in claim 45 wherein the reader is formed with a handle for holding the reader, detection unit and breath handler as the breath sample is being obtained.

47. The combination as set forth in claim 46 further in combination with a supply of urea in the form of at least one of: a bottle of urea and at least one tablet of urea.

48. A breath sampler for use in detecting the presence of H. pylori in the gastrointestinal tract, the breath sampler comprising a breath handler for receiving a breath sample from a subject, and a detection unit operatively connected to the breath handler for receiving the breath sample from the breath handler, the detection unit comprising a collection receptacle, a sensor membrane disposed in the receptacle capable of reacting to the presence of ammonia in the breath sample indicating the presence of H. pylori in the gastrointestinal tract, and a liquid in the collection receptacle generally covering the membrane, the liquid being capable of capturing ammonia from the breath sample to retain it in proximity to the sensor membrane.

49. A breath sampler as set forth in claim 48 wherein the liquid is water.

50. A breath sampler as set forth in claim 48 wherein the collection receptacle includes a bottom wall, the sensor membrane being disposed on the bottom wall and covered by the liquid.

51. A breath sampler for use in detecting the presence of H. pylori in the gastrointestinal tract, the breath sampler comprising a breath handler for receiving a breath sample from a subject, the breath handler including a mouthpiece portion having a breath sample opening in a distal end thereof, the mouthpiece portion being shaped for reception in a subject's mouth to locate the breath sample opening proximate the throat, and a detection unit operatively connected to the breath handler for receiving the breath sample from the breath handler, the detection unit including a sensor for detecting an indicator present in the breath sample of H. pylori in the gastrointestinal tract.

52. A breath sampler as set forth in claim 51 wherein the mouthpiece portion tapers in at least one dimension toward the breath sample opening.

53. A breath sampler as set forth in claim 52 wherein the mouthpiece portion tapers in cross sectional width and height.

54. A breath sampler as set forth in claim 53 wherein the breath handler comprises a tube including the mouthpiece portion and breath sample opening, and a collection branch extending from the tube to the detection unit, the mouthpiece portion extending from the collection branch to the breath sample opening and having a length selected to extend to the back of the subject's mouth.